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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Gregory Cope

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08/24/2006

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EXAMINER

PAK, YONG D

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/047,253	Applicant(s) COPE ET AL.	
	Examiner Yong D. Pak	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32,33,36,37,41-57,74,75,77 and 78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-33, 36-37, 41-57, 74-75 and 77-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on June 8, 2006, amending claims 32-33, and 77-78, has been entered.

Claims 32-33, 36-37, 41-57, 74-75 and 77-78 are pending and are under consideration.

Response to Arguments

Applicant's amendment and arguments filed on June 8, 2006, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The declaration under 37 CFR 1.132 filed June 8, 2006 is sufficient to overcome the rejection of claims 32-33, 36-37, 41-57, 74-75 and 77 based upon lack of written description and lack of enablement under 35 U.S.C. 112, first paragraph.

Sequence Compliance

Applicant is required to comply with the sequence rules by inserting the sequence identification numbers of all sequences recited within the claims and/or specification. It is particularly noted that the sequences in Figure 1-4 lack sequence identification numbers. See particularly 37 CFR 1.821(d).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-33 and 78 and claims 36-37, 41-57, 74-75 and 77 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32-33 and 78 recite the phrase "as set forth in". The metes and bounds of the phrase in the context of the claims are not clear. It is not clear to the Examiner if the recited polypeptide/peptide has the amino acid sequence of SEQ ID NO:2, 7, 23 and 24 or is a representative member of a genus. Examiner suggests amending the phrase as "the Rpn11 polypeptide comprising the amino acid sequence of SEQ ID NO:23 or 24" (claim 32), "the amino acid sequence... of SEQ ID NO:2" (claim 33) and "AMSH polypeptide comprises the amino acid sequence of SEQ ID NO:7 (claim 78) to clearly indicate that the polypeptide/peptide recited in the method has the amino acid sequence of SEQ ID NO:2, 7, 23 or 24.

Claims 32 and 78 and claims 33, 36-37, 41-57, 74-75 and 77 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32 and 78 and claims 33, 36-37, 41-57, 74-75 and 77 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32 and 78 recite the phrase "determining the isopeptidase activity of the test agent by measuring deconjugation of the modifier protein from the target protein". The metes and bounds of the phrase in the context of the above claims are not clear to the Examiner. It is not clear to the Examiner as to what applicants mean by "determining the isopeptidase activity of the test agent". Furthermore, it is also not clear as to how those skilled in the art can conclude that the agent identified by the above method modulates isopeptidase activity of Rpn11 or AMSH. It is not clear to the Examiner as to how applicants or those skilled in the art would recognize that said agent being tested is indeed specifically affecting isopeptidase activity of Rpn11 or AMSH and not directly causing the cleavage of the modifier protein from the target protein without affecting the isopeptidase. Therefore, the method lacks essential step(s).

In response to the previous Office Action, applicants have traversed the above rejection.

Applicants argue that since the claims have been amended to recite "determining isopeptidase activity of the test agent", the claims are definite. Examiner respectfully disagrees. The phrase "determining the isopeptidase activity of the test agent" is still not clear to the Examiner. The claimed method is not identifying the isopeptidase

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activity of the "test agent", but its ability to modulate isopeptidase activity of Rpn11 or AMSH.

Applicants also argue that since the 2nd paragraph of the claims 32 and 78 and the specification define what "deconjugation" is, the claimed method is definite with regard to how one skilled in the art can conclude that the agent identified by the claimed method modulates isopeptidase activity of Rpn11 or AMSH. Examiner respectfully disagrees. The rejection is not based on whether the phrase "deconjugation" is indefinite. Rather, the claimed methods are indefinite because it is not clear to the Examiner as to how applicants or those skilled in the art would recognize that said agent being tested is indeed specifically affecting isopeptidase activity of Rpn11 or AMSH and not directly causing the cleavage of the modifier protein from the target protein without affecting the isopeptidase. For example, when a test agent, Rpn11, modifier protein conjugated to a target protein are incubated, if the test agent cleaves the modifier protein from the target protein, according to the step of the claimed method, one would arrive at the incorrect conclusion that the test agent affects isopeptidase activity of Rpn11, whereas in actuality, the test agent does not affect the isopeptidase activity of Rpn11. The control step of measuring deconjugation in the absence of the test agent does not prevent said erroneous conclusion. Therefore, the claimed methods are indefinite because it is not clear to the Examiner as to how applicants or those skilled in the art would recognize that said agent being tested is indeed specifically affecting isopeptidase activity of Rpn11 or AMSH.

Hence the rejection is maintained.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 recites the phrase "an amino acid sequence as set forth in SEQ ID NO:2". The metes and bounds of this phrase in the context of the above claim are not clear to the Examiner. It is not clear whether the JAMM domain comprises a fragment of SEQ ID NO:2 or the full length of the amino acid sequence of SEQ ID NO:2. A perusal of the specification did not provide the Examiner with a specific definition for the above phrase. As applicants have not provided a definition for the above phrase, Examiner has interpreted the claims broadly to mean that a JAMM domain consisting essentially of "an amino acid ...as set forth in SEQ ID NO:2" encompasses fragments of SEQ ID NO:2. Examiner requests clarification of the above phrase and suggests amending the claim by replacing "an" with "the" in the above phrase.

In response to the previous Office Action, applicants have traversed the above rejection. Applicants argue that since the claim has been amended to recite "an amino acid sequence ofas set forth in SEQ ID NO:2", the claim is now definite. Examiner respectfully disagrees. It is still not clear whether the JAMM domain comprises a fragment of SEQ ID NO:2 or the full length of the amino acid sequence of SEQ ID NO:2. A perusal of the specification did not provide the Examiner with a specific definition for the above phrase. Examiner requests clarification of the above phrase and suggests amending the claim by replacing "an" with "the" in the above phrase.

Hence the rejection is maintained.

None of the claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

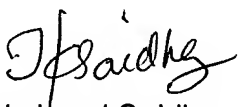
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak
Patent Examiner 1652


Tekchand Saidha
Primary Patent Examiner 1652